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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,673

10/08/2004

Katsuyoshi Nagao

040520

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05/23/2007

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

05/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/509,673	Applicant(s) NAGAO ET AL.	
	Examiner Phil Wiest	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,3 and 5-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/10/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. In the response filed 3/9/07, applicant amended claims 1 and 3. Claims 1, 3, and 5-24 are currently pending.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 16 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Iguchi et al. (US 6,232,128). Iguchi et al. discloses a bag that is capable of enclosing at least one multiple-chamber medical container, such as those disclosed in claims 1 and 3. Furthermore, said multiple-chamber medical container can be arranged in any position inside the bag.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 1 and 5-16 are rejected under 35 U.S.C. 103(a) as being anticipated by Inoue et al. (US 5,423,421) in view of Becker et al. (US 6,319,243).

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6. With respect to Claim 1, Inoue et al. disclose a multiple-chamber medical container comprising a container body 5 having multiple chambers (1, 7) capable of containing medicaments 10 therein, a partitioning seal portion (6c, 8a, 8b) for separating the chambers from one another, a medicinal outlet portion 2 attached to the container body 5 capable of discharging the medicaments, an openable small container 1A disposed in a larger chamber 7 and having a medicament 10 enclosed therein. Said partitioning seal portion (6c, 8a, 8b) is openable after the seal has been broken, enabling the chambers (1A, 1B) to communicate (Column 2, Lines 38-52) and is formed by bonding opposed inner wall surfaces together (Column 4, Lines 53-62). The sheet material 1 forming the small container 1A is bonded to the inner wall surfaces 6c of the container body on the right and left sides of the container 5 (see Figure 2). The small container 1A opens in accordance with the separation of the inner wall surfaces caused by the opening of the partitioning seal portion (6c, 8a, 8b) (Column 11, Lines 24-27). Inoue et al., however, does not disclose that the partitioning seal is operable so as to cause the multiple chambers (1, 7) to communicate with one another for use. Becker et al. discloses a container for mixing medical solutions comprising multiple large chambers (12, 14) and a smaller chamber 16. The small chamber 16 is in communication with one of the large chambers 14, and separated by a permeable seal (see Figure 1). Additionally, the larger multiple chambers are separated by a partitioning seal 18. The container of Becker et al. has the same functionality as the container of Inoue et al., except that the plurality of chambers are capable of being in fluid communication with one another, thereby enabling the selective mixing of up to

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three different fluids. Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the container of Inoue the multiple larger chambers of Becker et al. in order to allow a plurality of fluids to be mixed together in any desirable order.

7. With respect to Claim 5, Inoue et al. disclose that the small container 1A is adjacent to the partitioning seal portion (6c, 8a, 8b). See Figures 1 and 2. Inoue et al. further disclose a distance of about 5mm between the small container 1A and the side wall 6.

8. With respect to Claim 6, Inoue et al. disclose that the small container 1A is heat-sealed (Column 4, Lines 12-15), with the partitioning seal portion (6c, 8a, 8b) being openable by external force (Column 11, Lines 24-27). Additionally, a portion of the small container 1A is bonded to the inner wall surfaces at the right and left sides of the container (Figures 1 and 2)

9. With respect to Claims 7 and 8, Inoue et al. disclose that the bonded portion (6c, 8a, 8b) of the small container 1A comprises a plurality of bonded parts. Said bonded portion (6c, 8a, 8b) further comprises a non-bonded part 9 which is provided in the center of the bonded portion (6c, 8a, 8b), as per Claim 8.

10. With respect to Claim 9 and 10, Inoue et al. disclose a multiple-chamber medical container wherein the sheet material 6 of the small container 34 comprises a multilayer film (Column 4, Lines 12-15), wherein the small container is opened by delaminating the multilayer film (Column 11, Lines 22-27). Inoue et al. further disclose that said sheet material is formed by laminating a plurality of layers (6c, 8a, and 8b) having low

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miscibility together. Said layers are laminated together at said partitioning seal portion (6c, 8a, and 8b). See Figures 1 and 4.

11. With respect to Claim 11, Inoue et al. disclose that the layers of the small container 1A are laminated by a heat-sealing process (Column 4, Lines 12-15). The sealed portion (8a, 8b) is able to be reopened by an external force. (Column 11, Lines 22-27). See Figure 4.

12. With respect to Claim 12, Inoue et al. disclose that the small container 1A is disposed inside a larger chamber 7 and is capable of accommodating the medicament 10 in the chamber.

13. With respect to Claim 15, Inoue et al. disclose a powder 10 inside the small container 1A which may be an antibiotic (Column 9, Lines 52-54). Furthermore, the small container 1A is capable of holding any medicament selected from the group including antibiotics, anticancer drugs, cardiogenic drugs, vitamins, and trace elements.

14. With respect to Claim 16, the bag of Inoue in view of Becker is fully capable of being placed inside a bag and arranged in any position. If applicant amends the claims to add structure to the bag, the examiner reserves the right to impose a restriction requirement between the bag and the container.

15. Claims 3 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin (US 4,602,910) in view of Becker et al. (US 6,319,243).

16. With respect to Claim 3, Larkin discloses a multiple-chamber medical container comprising a container body 20 having chambers (11, 34) capable of containing

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medicaments 51 therein, a partitioning seal portion 44 for separating the chambers from one another, a medicinal outlet portion (25, 26) attached to the container body 20 capable of discharging the medicaments, an openable small container 34 disposed in a larger chamber 11 and having a medicament 50 enclosed therein. Said partitioning seal portion 44 is openable after seal 43 has been broken, enabling the chambers (11, 34) to communicate (Column 4, Lines 9-21) and is formed by bonding opposed inner wall surfaces in a way such that they are separable (see Figures 4 and 5). The sheet material (36, 37) forming the small container 34 is bonded to the inner wall surfaces (15, 18) of the container body within the partitioning seal portion 44 (see Figure 4). The small container 34 opens in accordance with the separation of the inner wall surfaces (15, 18) caused by the opening of the partitioning seal portion 44 (see Figure 5). Larkin, however, does not disclose that the container comprises multiple chambers, with an additional small container disposed within at least one of said multiple containers.

17. Becker et al. discloses a container having a plurality of chambers (12, 14) and a smaller chamber 16 that communicates with one of the chambers 14 when the seal 20 is broken. Additionally, the chambers are separated by a partitioning seal 18. The container of Becker et al. has the same functionality as the container of Larkin, except that it has a plurality of chambers, thereby enabling the selective mixing of up to three different fluids (see Figure 1). Therefore, it would have been obvious to one skilled in the art at the time of invention to combine the container with Larkin with the multiple larger chambers of Becker et al. in order to allow a plurality of fluids to be mixed together in any desirable order.

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18. With respect to Claim 17 and 18, Larkin discloses a multiple-chamber medical container 20 wherein the sheet material of the small container 34 comprises a multilayer film (15, 18, 36, 37), wherein the small container is opened by opened by delaminating the multilayer film. Larkin further discloses that said sheet material is formed by laminating a plurality of layers (15, 18, 36, 37) having low miscibility together, as per Claim 18. Said layers are laminated together at said partitioning seal portion 44. See Figures 4 and 5.

19. With respect to Claim 19, Larkin discloses that the layers of the small container are laminated by a heat-sealing process (Column 6, Lines 35-39). The sealed portion 44 is able to be reopened by an external force (Column 4, Lines 9-21). See Figures 4 and 5.

20. With respect to Claims 20 and 21, the small container 34 is disposed inside the large chamber 11 and accommodates the medicament 50 in the chamber (Column 3, Lines 39-41). Regarding Claim 21, Larkin further discloses that the medicament outlet portion (25, 26) is connected to the chamber 11 having the small container 34 disposed within. See Figure 1.

21. With respect to Claim 22, a discharge-control seal portion (27, 28, 32) is provided as an openable partition between the chamber 11 and the medicinal outlet portion (15, 16) (Column 3, Lines 53-56). See Figure 1.

22. With respect to Claim 23, Larkin discloses that antibiotic powder 50 may be used as the medicament (Column 3, Lines 40-41). Furthermore, the small container 34 is

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container is capable of holding any medicament selected from the group including antibiotics, anticancer drugs, cardiogenic drugs, vitamins, and trace elements.

23. With respect to Claim 24, the bag of Larkin in view of Becker is fully capable of being placed inside a bag and arranged in any position. If applicant amends the claims to add structure to the bag, the examiner reserves the right to impose a restriction requirement between the bag and the container.

24. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Larkin.

25. With respect to Claim 13, Inoue et al. disclose a multiple-chamber medical container comprising a container body 5 having chambers (1A, 1B, 7) capable of containing medicaments 10 therein, a partitioning seal portion (6c, 8a, 8b) for separating the chambers from one another, a medicinal outlet portion 2 attached to the container body 5 capable of discharging the medicaments, an openable small container 1a disposed in a larger chamber 7 and having a medicament 10 enclosed therein. Inoue et al., however, does not disclose that the medicinal outlet portion is in direct communication with the small container. Larkin discloses a multiple-chamber medical container wherein the medicinal outlet portion (25, 26) is connected to the chamber having the small container 34. It would have been obvious to one skilled in the art at the time of invention to combine the multiple-chamber bag of Inoue with the small container positioning of Larkin because the small container of Inoue is disclosed as

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being in fluid communication with the compartment comprising the fluid outlet. Since the exact placement of the small container does not affect the functionality of the system, placement within said compartment would have been obvious. Therefore, as disclosed by Larkin, the placement of a small, openable medicament container within a bag that is in fluid communication with the outlet is well known in the art.

26. With respect to Claim 14, Inoue et al. disclose a multiple-chamber medical container comprising a container body 5 having chambers (1A, 1B, 7) capable of containing medicaments 10 therein, a partitioning seal portion (6c, 8a, 8b) for separating the chambers from one another, a medicinal outlet portion 2 attached to the container body 5 capable of discharging the medicaments, an openable small container 1a disposed in a larger chamber 7 and having a medicament 10 enclosed therein. Inoue et al., however, does not disclose a discharge-control seal to control flow out of the medicinal outlet portion. Larkin discloses a multiple-chamber medical chamber comprising a discharge-control seal (27, 28, 32) provided as an openable partition between the medicinal outlet portion (25, 26) and the chamber 11. It would have been obvious to one skilled in the art at the time of invention to modify the multiple-chamber medical container with the discharge control seal (27, 28, 32) of Larkin in order to prevent fluid flow through the outlet at an undesirable time. The use of a seal or valve at the fluid outlet of the bag is well known in the art.

Response to Arguments

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27. Applicant's arguments with respect to claims 1, 3, and 5-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
5/17/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

